

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO**

ROXANE LABORATORIES, INC.,

Plaintiff,

v.

CAMBER PHARMACEUTICALS, INC. and
INVAGEN PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. _____

DEMAND FOR JURY TRIAL

COMPLAINT FOR PATENT INFRINGEMENT AND INJUNCTIVE RELIEF

Plaintiff Roxane Laboratories, Inc. (“Roxane”), for its Complaint against Defendants Camber Pharmaceuticals, Inc. (“Camber”) and InvaGen Pharmaceuticals, Inc. (“InvaGen”), alleges as follows:

PARTIES

1. Roxane is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.
2. On information and belief, Camber is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 1031 Centennial Avenue, Piscataway, New Jersey 08854.
3. On information and belief, InvaGen is a corporation organized and existing under the laws of the State of New York, with its principal place of business at 7 Oser Avenue, Hauppauge, New York 11788.
4. On information and belief, Camber and InvaGen sell generic drugs throughout the United States, including in at least Ohio.

NATURE OF ACTION

5. This is a civil action for infringement of United States Patent No. 8,563,032. This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a) because it arises under the patent laws of the United States.

7. This Court has personal jurisdiction over Camber because, *inter alia*, Camber has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Roxane, a company with its principal place of business in this forum. This Court has personal jurisdiction over Camber for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. The Court has personal jurisdiction over Camber due to, *inter alia*, Camber's systematic, purposeful, and continuous contacts in this district. On information and belief, Camber has purposefully availed itself of this forum by making, shipping, using, offering to sell, or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of Ohio and deriving revenue from such activities.

9. This Court has personal jurisdiction over InvaGen because, *inter alia*, InvaGen has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Roxane, a company with its principal place of business in this forum. This Court has personal jurisdiction over InvaGen for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

10. The Court has personal jurisdiction over InvaGen due to, *inter alia*, InvaGen's systematic, purposeful, and continuous contacts in this district. On information and belief, InvaGen has purposefully availed itself of this forum by making, shipping, using, offering to sell, or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of Ohio and deriving revenue from such activities.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because, *inter alia*, this Court has personal jurisdiction over Camber and InvaGen and on information and belief, Camber and InvaGen have committed, and made meaningful preparations to commit, acts of infringement in this District. Venue is also proper because Roxane resides in this judicial district.

THE PATENT-IN-SUIT

12. On October 22, 2013, the United States Patent and Trademark Office (the "PTO") lawfully issued Patent No. 8,563,032 (the "'032 Patent"), entitled "Formulation and Manufacturing Process for Calcium Acetate Capsules." A true copy of the '032 Patent is attached hereto as Exhibit A. Roxane is the record assignee of the '032 Patent.

13. The '032 Patent claims, *inter alia*, novel formulations of calcium acetate capsules. Calcium acetate capsules are used to control hyperphosphatemia in patients suffering from end stage renal failure.

ROXANE'S GENERIC CALCIUM ACETATE PRODUCT

14. Roxane submitted Abbreviated New Drug Application ("ANDA") No. 77-728 to the Food and Drug Administration ("FDA") to market a generic form of calcium acetate capsules (the "Roxane Calcium Acetate Product") for the reduction of serum phosphorous in patients with end stage renal disease. The invention(s) disclosed in the '032 Patent arose out of Roxane's substantial and successful effort to develop the Roxane Calcium Acetate Product.

15. The FDA approved Roxane's ANDA No. 77-728 in 2008, and thereafter, Roxane began marketing the Roxane Calcium Acetate Product. Up to the time of Defendants' infringing activities, the Roxane Calcium Acetate Product has been the only true generic version of calcium acetate capsules available on the market in the United States.

INVAGEN'S GENERIC CALCIUM ACETATE PRODUCT

16. On information and belief, InvaGen filed ANDA No. 20-3135 seeking FDA approval for a generic calcium acetate capsule product (the "InvaGen ANDA Product").

17. On information and belief, Camber and InvaGen collaborated and acted in concert in the decision to file and the filing of ANDA No. 20-3135.

18. On information and belief, by filing ANDA No. 20-3135, Camber and InvaGen evidenced that upon FDA approval, they intended to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the InvaGen ANDA Product.

19. On information and belief, the FDA approved ANDA No. 20-3135 on February 7, 2013.

20. Camber and InvaGen have begun marketing and offering for sale and/or selling the InvaGen ANDA Product. Camber and InvaGen have offered the InvaGen ANDA Product to customers and have booked sales for that product for distribution in the United States, including this judicial district.

21. Roxane gave InvaGen actual notice of the '032 Patent and from that date has sought samples of the InvaGen ANDA Product or any other information that would assist Roxane in confirming whether the InvaGen ANDA Product is within the scope of one or more claims of the '032 Patent.

22. In response to Roxane's requests, and under the protection of a confidentiality agreement, InvaGen provided to Roxane information purporting to describe the InvaGen ANDA

Product. Prior to this Complaint, InvaGen declined to provide Roxane with any samples of the InvaGen ANDA Product itself.

COUNT ONE

(Infringement of U.S. Patent No. 8,563,032)

23. Roxane reasserts and realleges paragraphs 1-22 above as if fully set forth herein.

24. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of InvaGen's ANDA Product infringes one or more claims of the '032 Patent.

25. On information and belief, based on standard industry practice, Camber and InvaGen have engaged in activities for manufacturing, distributing, offering to sell, selling, and importing the InvaGen ANDA Product.

26. Camber and InvaGen have offered the InvaGen ANDA Product for sale, and have sold that product for distribution in the United States, including this judicial district.

27. On information and belief, such activities have infringed, or imminently will infringe, one or more claims of the '032 Patent.

28. Defendants are jointly and severally liable for infringement of the '032 Patent. Upon information and belief, Camber participated in, contributed to, aided, abetted, and/or induced InvaGen to engage in activities in preparation for manufacturing, distributing, offering to sell, selling, and importing of the InvaGen ANDA Product.

29. Roxane will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff does not have an adequate remedy at law.

30. Roxane requests a trial by jury for every issue so triable as of right.

PRAYER FOR RELIEF

WHEREFORE, Roxane respectfully requests the following relief:

A. A judgment that Defendants have infringed the '032 Patent;

B. A preliminary and permanent injunction restraining and enjoining InvaGen and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of the InvaGen ANDA Product until the expiration of the '032 Patent;

C. An order awarding Roxane monetary relief for Defendants' past, ongoing, and/or future infringement of the '032 Patent, in an amount and under terms appropriate under the circumstances;

D. An order declaring that Defendants' infringement is and/or will be willful, warranting increased damages under 35 U.S.C. § 284;

E. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: March 4, 2014

Respectfully Submitted,

/s/ Drew H. Campbell

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Admission *pro hac vice* pending.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 4, 2014, a true copy of the foregoing was filed electronically. Notice of this filing will be sent to all registered parties by operation of the Court's CM/ECF filing system. Parties may access this filing through that system.

/s/ Drew H. Campbell

Drew H. Campbell